SIEMENS

MAMMOMAT Balance

SP

Start-up

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Document revision level

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General Information

1. Required documents

- Installation and Start-up Instructions SPB7-115.814.01….
- Instructions for use SPB7-115.629.01….
- Service Instruction SPB7-115.840.01….

2. Required tools, measurement and auxiliary devices

- Oscilloscope
- Oscilloscope probe 1:100 > 600Vdc
- Digital multimeter
- Non invasive kVp-meter (mammo)
- Dosemeter (mammo)
- Service PC with serial port (connection cable is supplied with the unit)
- MAMMOMAT Balance SSW (Service Software Program is supplied with the unit)
- SIB phantom or Normi 7 or 4 cm Plexi or customer phantom (supplied by customer)
- Sensitometer / Densitometer
- Film pack 18x24 and 24x30 if it occurs
- Standard installation tools
- Plexiglas phantom 2cm, 2cm, 2cm, 1cm, 0.5cm for AEC calibration (supplied with the unit)

3. Preliminary

During Start Up no calibrations are requested other than AEC linearity.

Generator functionality check and performances can be inspected according to the following essential procedure or more in detail following a specific QA protocol if requested in the specific country of installation.
AEC calibration software has online Help for software functions and calibration instructions.

Manual mode check

Set Up the unit for “NORMAL BREASTS EXAMINATION” as described in the Operator’s manual .
Select Manual mode, 28kV, 50mAs, put in place 4cm Phantom and take one picture with Large Focus and one with Small focus.
Measure O.D. on both films it must be identical, record operating conditions plus O.D. on each film and keep films in file for future reference.

1. -kV check

Remove compression paddle and potter bucky, select large focus and Mo filter if unit has automatic Mo/Rh filter and check kV with non invasive kVp meter.
If non invasive kVp meter is not available, check kV with DVM as described in Service Instruction SPB7-115.840.01….
For more details about kV check and/or eventual kV adjustment, refer to Service Instruction SPB7-115.840.01….

2. -mA check

mA check/calibration is not necessary if no alarm “Low anode current” is generated after exposure.
If necessary refer to Service Instruction SPB7-115.840.01….

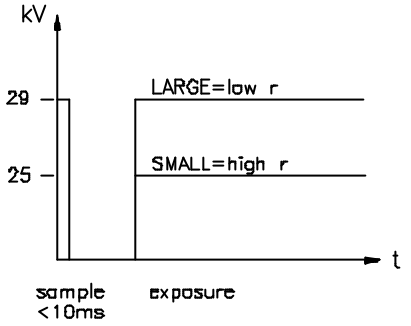
3. -mAs check

mAs can be checked as product of mA by exposure time by means of oscilloscope connected to R16 of PCB 92-073 filament power supply.
More effective mAs check, can be performed as mAs/mGy ratio by means of external Dosemeter.
For different mAs setting on the control panel record related dose in mGy and check that ratio remains constant within 5% maximum (max tolerance by IEC standard = 20%)

Automatic mode check

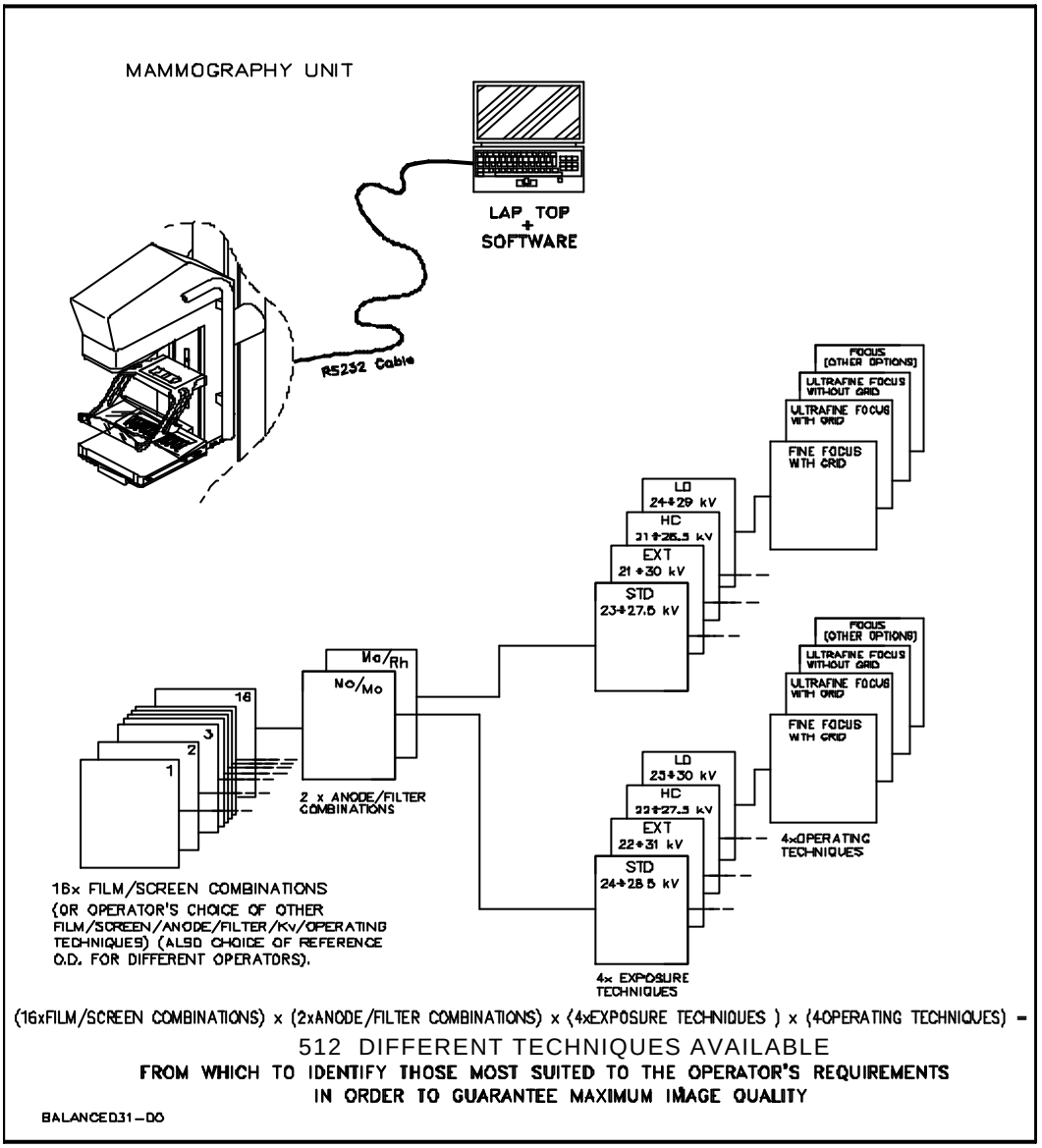
1. Things to know before to start

The unit has an Automatic Exposure Control (AEC) that is among the most advanced available on the market today.
Operation of the AEC is based on the effective breast density measured by means of a very short "pre-exposure" x-ray pulse.
This is the best way to operate the AEC exceeding performances of other systems only based on breast thickness evaluation.
The radiation [r] read by the detector during pre-exposure represent breast density and after being converted to a number that is inversely proportional to it, will be used in the process of exposure control that will continue in a completely numeric form, except for the Dose integration.



The above figure shows a time schematization of the exposure concept in ZERO POINT technique, with completely automatic kV and mAs.

The parameter [p] derived directly from the [r], the density of the breast being examined, is used as a pointer on two look-up tables containing the kV and mAs necessary for obtaining an image with the right blackening and contrast to fully satisfy any Quality Protocol in the Mammography field today.
A high value [p] corresponds to a LOW Density Breast and low values of kV and mAs are delivered.
A low value [p] corresponds to a HIGH Density Breast and high values of kV and mAs are delivered.
kV values can't be modified, but four different ranges are made available to the operator, with different kV profiles suited to different requirements that go beyond the possibilities offered by the well-known High Contrast (HC) and Low Dose (LD) techniques.
From the control panel, the operator can not only select the technique that he feels most suitable but he can also make fine-tuning in steps of 0.5kV on the kV range selected.



The above figure is a diagram of the operating possibilities of the DEATA PLUS software with Mo target / Mo filter or Mo target with automatic Mo/Rh filters.

The large number of Film Screen and techniques available have to be intended to give the possibility to tune the system to the specific requirements of any single or multiple user and or different film that can be momentarily found in critical markets without loosing the possibility to go back to the previously used when newly available.

2. Mammography system

Mammography unit, Film, X-ray Cassettes and Screen, Film Processor and Chemicals are the components that all together make up one SINGLE SYSTEM, the final product of which is the X-ray image.
To obtain a good X-ray image, each component of the SYSTEM plays a determining role and must be appropriately managed and integrated with all the others.

No system is able to provide results fulfilling the requirements of any existing Quality Control protocols without an appropriate calibration that takes into consideration all the specific characteristics of each single components.
The aim of this procedure is to integrate the system components for obtaining the requested Optical Density and linearity over the widest range of breast density.

3. Selecting film/screen combination

Some key information will be provided below on how to obtain a good image with minimum dose.

For maximum image quality, it is advisable to use only film/screen combinations recommended by the manufacturer.
The United States regulations have made this recommendation a Must.
The X-ray cassettes for mammography use have only one intensifying screen that converts the X-rays to light that impresses the image on film.
Every screen has its own x-ray/light conversion factor that must be suited to the film to be used.
Films for mammography use are single emulsion and have various sensitivities and contrasts.
An appropriate choice of these products is reflected in image quality.
We leave this responsibility to the user, dutifully pointing out the difference that it can represent in terms of x-ray Dose delivered to the patient.

Large Focus with Grid						
	MR5 + DETAIL			MINRH + MINR		
Cm	KV	mAs	R	kV	mAs	R
5.5	28.0	480	23	28.0	190	24

The tables shows mAs for the same Optical Density on 5.5 cm of Plexiglas, using two different films/screens.
The difference is considerable: 480/190=2.5 times!

4. Film Processor

Film for mammography use has treatment characteristics that are very specific and different from those used for other film.
A dedicated Processor is highly recommended for treating mammography film, which guarantees temperature and development time suited to the specific film.
Development temperature is generally between 34 and 35 °C and has a marked influence on the radiological dose necessary to obtain the required O.D.

PROCEDURE PREPARATION

1. Software installation

Have software installed and serial port connection checked before starting the procedure.

2. Developer

The developer must be in perfect conditions for use with developing and fixing replaced a day beforehand.

3. X-ray cassette for tests

Select and mark a cassette that will be the only one used for all the tests.
If possible, select the cassette with optical density as close as possible to the average measured on all those available.

4. Film pack for tests

Make sure that there is enough film in the pack being used to complete the procedure, otherwise open a new pack.

5. Test dummy

A Plexiglas test dummy is supplied with each unit, made up of three 2 cm layers, one 1 cm layer and one 0.5 cm layer.
In each layer there is a small steel sphere placed at an increasing distance from the left edge.
These spheres identify the layers in order to guarantee that the position and the composed layers can be repeated and guarantee the best repeatability of x-ray attenuation.

6. O.D. reference X-ray

Expose a film in Manual Mode 28kV technique, with a 4 cm dummy with optical density between 1 and 2.
If during the procedure Processor stability is in doubt , repeat the same X-ray to quickly estimate O.D. repeatability.

7. Time for carrying out procedure

For best results, it is recommended to carry it out without interruptions for lunch or other.

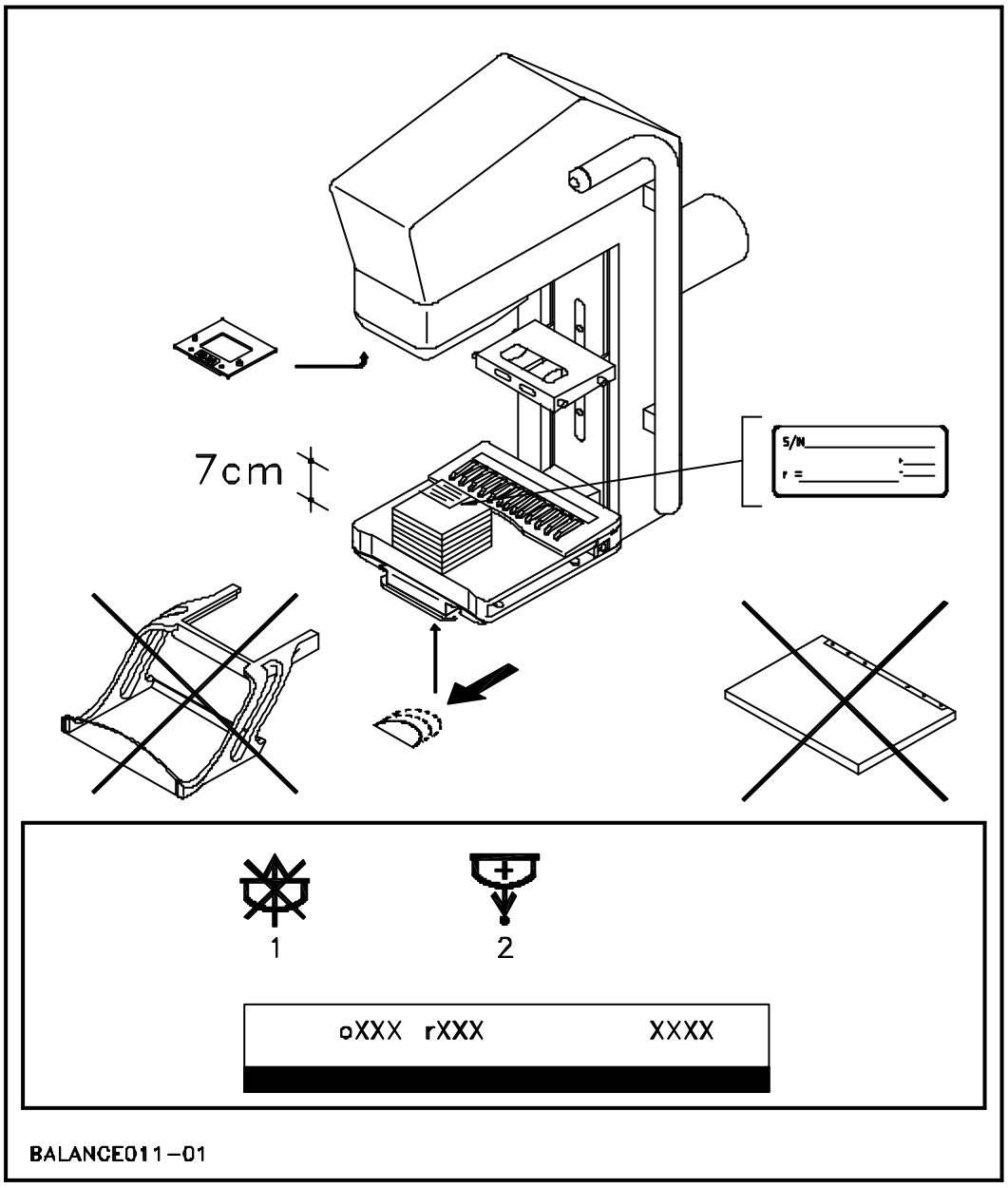
8. Anode filter combination

If the unit has an automatic Mo/Rh filter manually select the correct Fix configuration from the control panel in order to avoid automatic selection of filter or anode at higher phantom thickness.

9. Detector calibration

Detector sensitivity is of maximum importance in order to guarantee the correct dynamic and correspondence of the exposure parameters.
To facilitate control and calibration of parameter [r] each unit has a plain block of Plexiglas (dummy) for a rapid control and a simple periodical re-calibration. The dummy is a relative reference that is characterized vs. an absolute reference during factory calibration.
The dummy is an integrating part of the unit, can be used also by the operator and must always be available to the operator throughout time.

For [r] testing, the system must be configured as shown:



- Install Grid table 18x24 83 83 171
- Install 18x24 83 83 205 collimation plate
- Select LARGE focus
- Remove compression plate

- Remove cassette
- Select ZERO POINTS technique
- Disable potter bucky by inhibiting compressor release at exposure end and pressing the "Compression +" key
- Position detector at first stop on patient side
- Position the 7-cm-thick Phantom so as to completely cover the detector.
- Repeat the test for each one of the three fields.

This configuration was selected in order to eliminate all the variable components that could be placed between the beam source and the detector.

Carry out an exposure and then check that [r] value is within ±10 of the value from the phantom label.
At the same time check that [o] value is not 0 (zero) or higher than 12.
If out of range adjust according to the following points 10 and 11.
Normal operating condition is restored when cassette is inserted in the table.

10. OFFSET [o] CALIBRATION

The value of the detector offset appears in the lower left of the display when Test mode is selected.
The offset value depends on the temperature.
The value must be checked after at least 5 minutes from turning the unit on and it should be 10±5 .
The system loses its linearity if the value reaches zero or exceeds 20.
When adjusting GAIN [r] or Offset [o], large variations of one of them can affect the other, check both and eventually correct before to leave calibration.

11. DETECTOR [r] GAIN CALIBRATION

Value of [r] depends on:
a) Precision of the kV value
b) Precision of the mA anodic current
c) Detector gain calibration.
Before proceeding with gain calibration, make sure that the values referred to in points a) and b) are correct.
The value of [r] appears in the lower left of the display when Automatic Mode is selected.

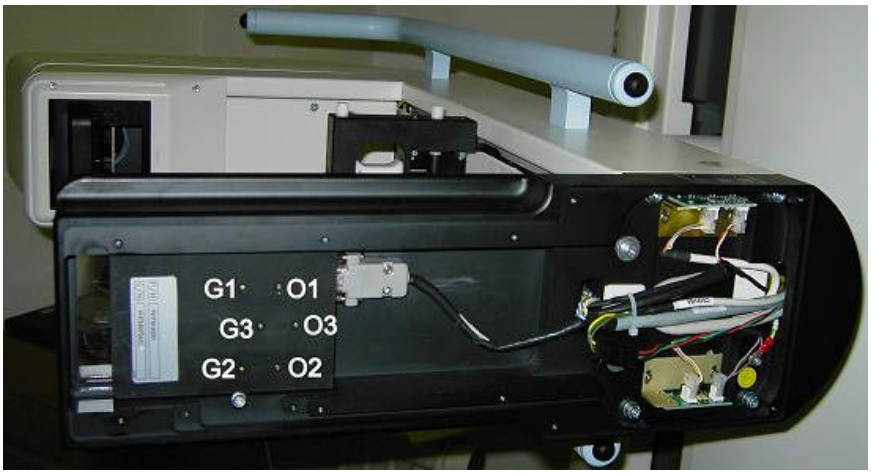
The value must be checked after at least 5 minutes from turning the unit on and it should be the same as the value shown on the test dummy +/-10.
O ➔ offset; G ➔ Gain ([r] on the display).

Turning offset clockwise ➔

➔ increases

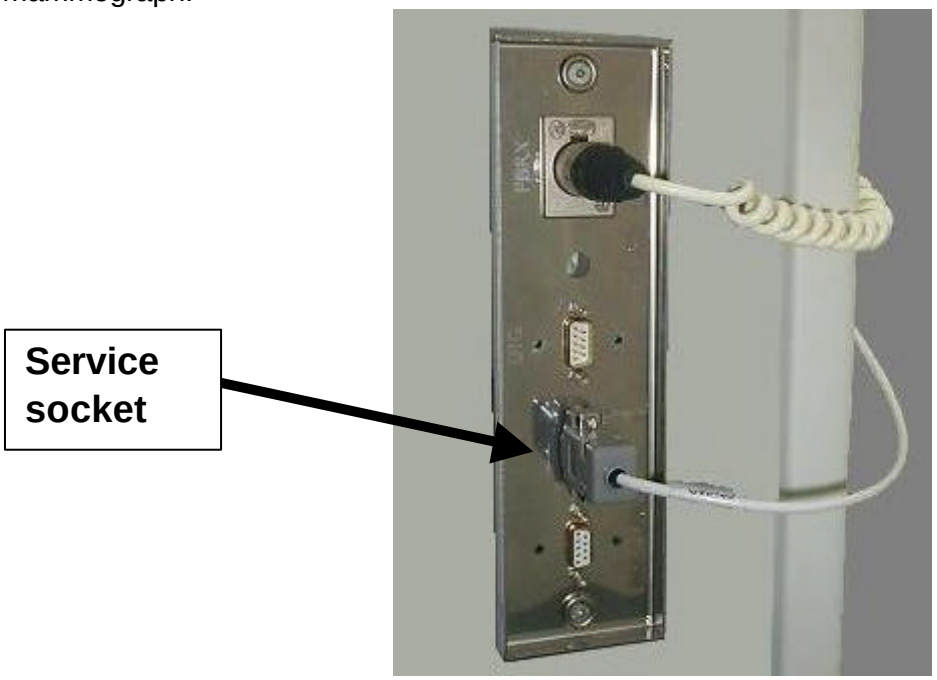
Turning gain clockwise ➔

➔ increases



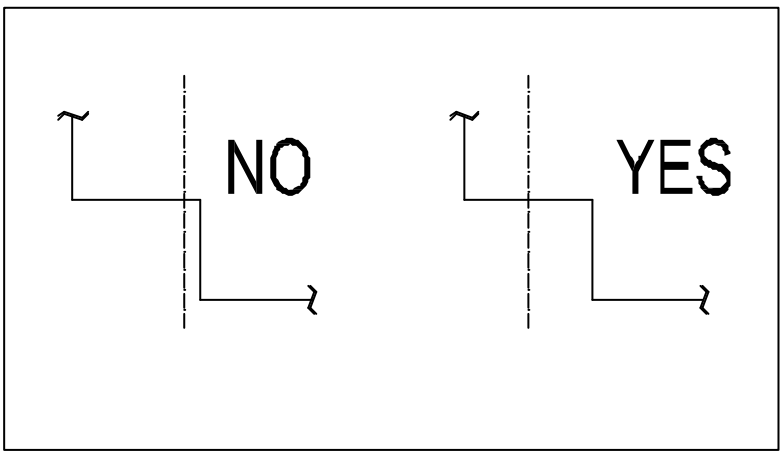
12. Connecting PC for calibration

To connect the PC to the MAMMOMAT Balance, insert the serial cable into the service socket on the back side of the mammograph.



13. Selection of test layers

For the best overall results it's important that Zero Point calibration is carried on in the most accurate conditions.
The minimum procedure is based on three thicknesses, 2, 4, 6 cm.
Before starting the procedure with Films, some "dry" test (cassette inserted but no film) must be performed to find the most appropriate phantom thicknesses +/-5mm, the related value of [p] must be checked to see that it is **as much close to the center of a kV value, and not near the margin between two kV values.**
If this point does not fall in the middle of the kV interval, there can be a difference of 0.5 kV between successive exposures; this MUST be avoided.
For checking, refer to the specific range and kV steps of the technique currently under calibration (STD, HC, LD, EXT), focal spot and anode/filter combination.



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Use the 5mm Plexiglass layer or even remove/insert the compression plate in order to accommodate p (plog)
Repeat the test for all thicknesses that are to be used.

14. Other Techniques and operating modes

Every operating mode has its own independent calibration.

15. Automatic Molibdenum Rhodium filter

If the unit is equipped with an automatic Mo/Rh filter, filter selection is automatic and depends on breast density, verified during pre-exposure.
The TRIP POINT **T** can be programmed, but it is not advisable to change it unless there are well-evaluated reasons based on the statistical readings based on the last 1300 exposures.
For the Rhodium filter, the calibration curve of the relative Anode Filter combination must be programmed.
During calibration of this curve, bear in mind that the part of the curve used will be more to the right, beyond the relative **p** value at the threshold point **T**.
A part of the curve to the left of the **T** point could nevertheless be used if the operator has manually selected the Rhodium Filter.

16. Modification of the reference Density after calibration

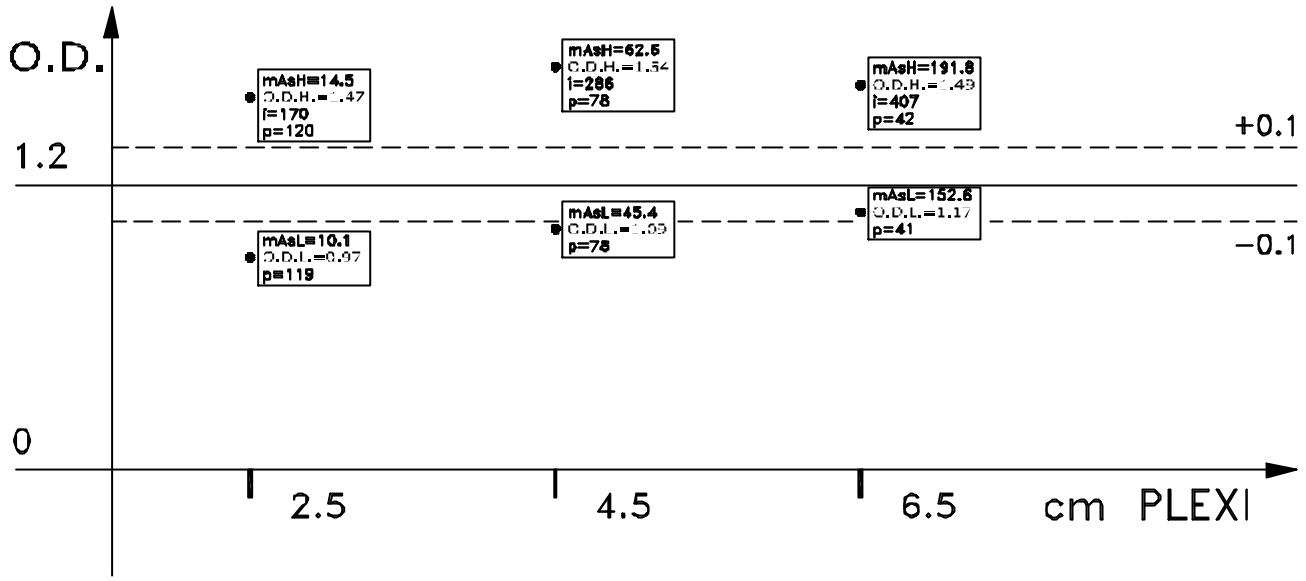
Each calibration curve and related reference O.D. can be corrected to get it lighter or darker by means of option (O) to add or subtract a percentage value to move the calibration curve up or down, giving rise to an increase or a decrease of O.D..

17. Maximum breast density limit

With the DEATA PLUS software, it is possible to define a maximum work limit (LOW p) defined as maximum breast density, to interrupt exposure after the sampling impulse, releasing a dose of less than 1 mAs.
The limit is defined according to the specific characteristics of each single installation, in order to avoid releasing excessive doses, which could make the Film unusable as a consequence of unforeseeable operating errors, such as an undeclared silicone prosthesis. In this case the AEC ERROR alarm is generated.

18. Calibration concept

Deata Plus procedure is based on two films for each phantom thickness having O.D. Higher and Lower than selected reference value as described in the following drawing.



Phantom thickness for test are minimum 3.
Automatic data collection, interpolation and curve smoothing are provided, operator has only to measure and input O.D.
Automatic procedure is also provided to generate Manual Density Steps after that Zero Point curve has been generated by means of automatic procedure.
One point mode calibration is the last operation and can be performed for kV and Phantom Thickness specified in the applicable protocols.

19. Linearity check

After calibration, linearity check must be performed to verify that all what you did was correct.
After setting the Manual Density command to ZERO, make one exposure for each dummy thickness and kV specified in the quality protocol
If something needs to be fine adjusted, tools are provided for manual calibration of specific points.

20. Unused Operating Technique and Film Screen

In order to avoid operating errors and misunderstandings to the operator, if only one Film Screen and Operating Technique, STD, EXT, HC, LD has been calibrated, all the others can be disabled by means of DIP 5 SW1 PCB 01-170.
If more than one Film Screen and Operating Technique are calibrated and available for normal use, the above function can't be used, refer to next paragraph.

21. Disabling specific Operating Technique and/or Film Screen

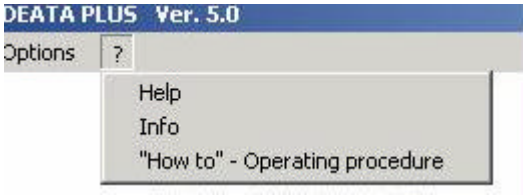
Disabling an Operating Technique or the entire Film Screen is done by storing the relative curve or curves with the value of **i=0** for the first pair of values that correspond to **p = 0**.
Tempted exposure with Techniques with a curve that has **i=0** for **p=0** does not start tube rotation and generates the message "**TECHNIQUE NOT PROGRAMMED**"

CALIBRATION PROCEDURE

Two different online Help are available

? Help for software functions

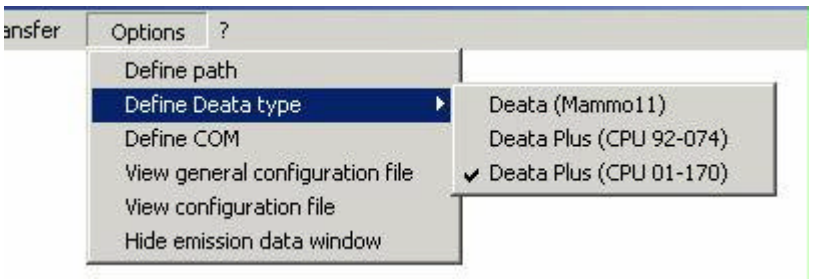
? “How to” for procedure description



? Open or Create calibration file as described in Deata Plus Help

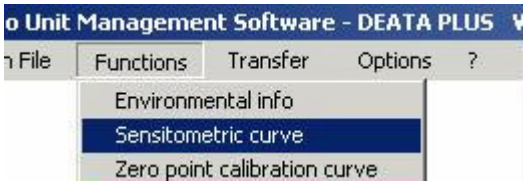
.

? Verify that appropriate Deata Type is defined according to the configuration of the specific unit you have to calibrate.



? Take note of Environmental Conditions for future reference

? Process and record data from a Sensitometric strip

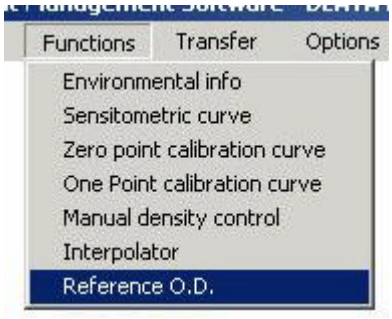


? Configure Mammo unit for the Operating Technique to calibrate.
Take an exposure to check that a calibration curve is already stored in the unit, so that the exposure parameters appear in the “Emission data” window.
If “Technique not programmed” alarm comes out, default calibration curve must be stored before to go ahead with calibration.

Press Download

Repeat test exposure to check that calibration curve is now available.
Check for appropriate phantom thickness as described in chapter “Procedure Preparation”, paragraph “Selection of test layers”.

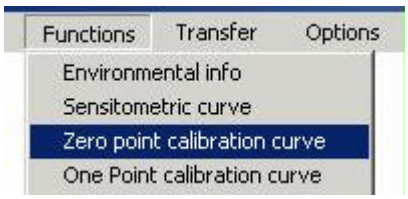
? Select Reference O.D. for calibration



Reference O.D. can also be selected later from inside Zero point calibration curve procedure.

1. Zero Point calibration

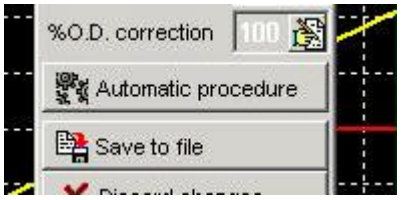
? Select Zero Point calibration curve



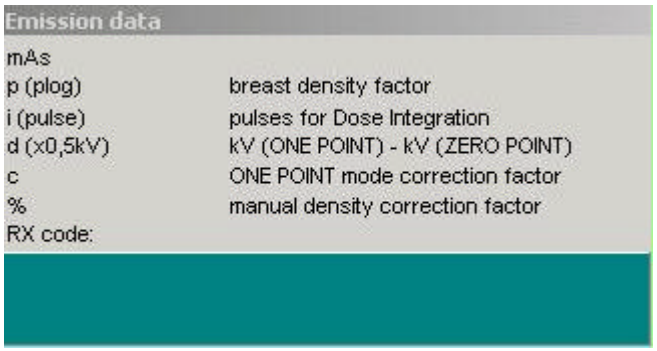
and start procedure from one of the phantom thicknesses having Manual Density set to ZERO on the control panel of Mammo unit.

Two different calibration possibilities are available: Automatic and Manual
Automatic mode is recommended as most powerful tool giving access to other automatic functions of this calibration software.
Manual calibration is only provided for expert technicians to perform special tasks.

Automatic

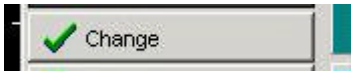


exposure parameters



are automatically recorded in the table

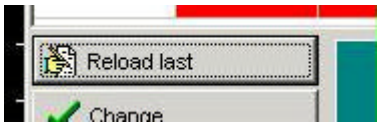
after keyboard input of measured O.D.
Parameters are recorded as High values if O.D. is higher than reference and vice versa.
If first O.D. for a given thickness il Low, next exposure must have Manual density set to +1 or more depending on how much difference exists between Reference O.D. and last exposure.
If O.D. was higher than reference, set Manual Density to -1 or more.
When High and Low values are complete change to the next thickness and repeat the procedure.
A minimum of two phantom thickness is necessary before to get the Change button green, but for the best results a minimum of three phantom thickness is required.



After clicking the Change button, calibration curve is automatically reshaped.

To accept click Save to File and transfer new curve to the unit ().

Values in the table are saved to file and can be recalled by means of Reload Last button



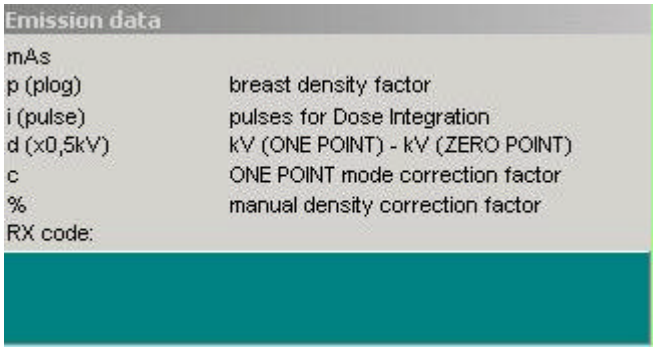
to complete or modify calibration curve.

Important NOTE
If default curve used for calibration is too much different from characteristics of Film/screen to be calibrated, may happen that manual density adjustment is not wide enough to obtain High and Low densities for each phantom thickness.
In such circumstance it's necessary to modify the default curve and store it again in the unit before to proceed with next points/thickness.
Calibration curve can be modified editing points manually or by means of %O.D. correction

the same concept remains valid for next Manual procedure.

Manual

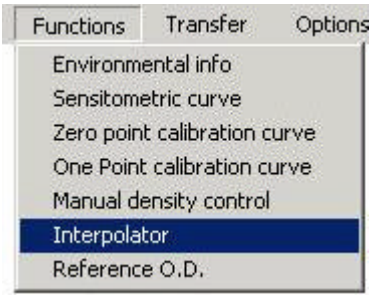
exposure parameters



have to be manually recorded into calibration forms,

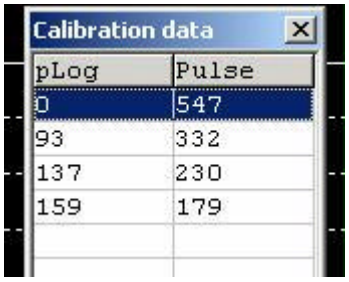
	parameters for O.D.>				*Parameters for O.D.<*		
cm	***mAsH***	***O.D.H***	***Pulse(i)***	***plog(p)***	***mAsL***	***O.D.L***	***plog(p)***

processed by means of Log Interpolator,



Cm	mAs	pulse(i)	plog(p)	O.D.

to obtain coordinates Plog (p) and Pulse (i) to build up the calibration curve.



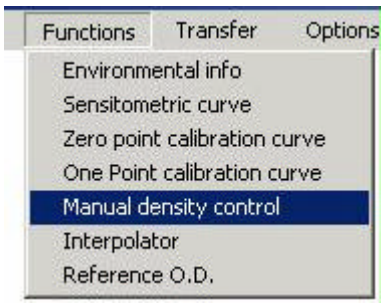
In Manual calibration procedure curve shape must be manually adjusted for plog = 0 and plog = 159 being the extremities of the curve.

? For each phantom thickness used for calibration, make a test exposure and check that O.D. is now within requested tolerance.

Cm	MAs	KV	O.D.	Plog(p)	pulse(i)

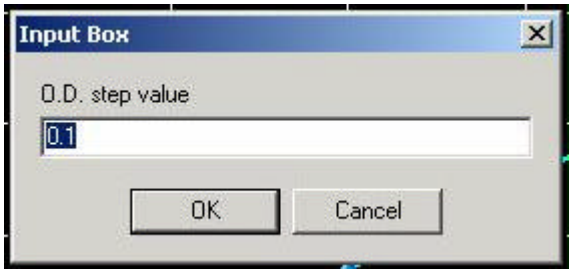
2. Manual Density steps

? Select Manual density control

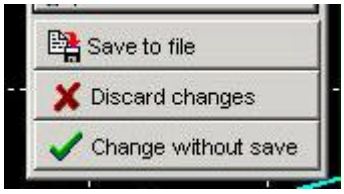


select automatic

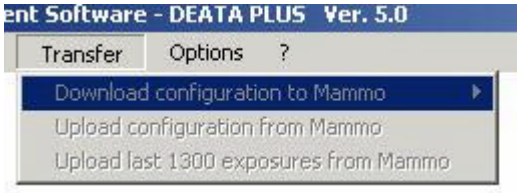
define O.D. step change



and click OK. Table will be automatically changed.



Save to file and transfer new data to the unit



Check with exposures that step O.D. changes according to selected value.

3. One point calibration

In One point mode kV are selected by the operator and for a given thickness they can be

< than kV in zero point mode (dkV between -14 and -1), or
> than kV in zero point mode (dkV between +1 and +10).
If they are > than kV in zero point mode, they can also be:
< than 30 kV
>= of 30kV.

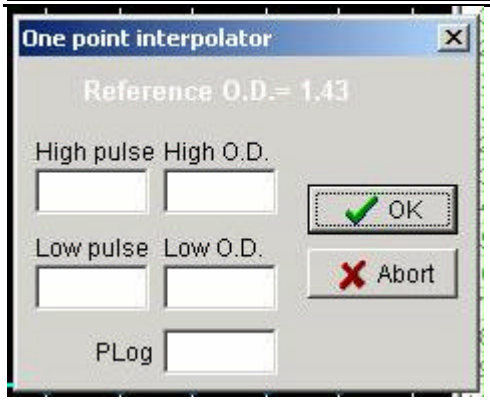
For each specific condition correction factors % are defined to compensate O.D. in function of kV difference between Zero (CPU) and One point (operator).

Select % value to change in the appropriate column. If after exposure, d parameter from communication window was +2 , One point was 2 kV higher than Zero point kV

dkV	<kVOP	<30kV	>=30kV
-14	100		
-13	100		
-12	100		
-11	100		
-10	100		
-9	100		
-8	100		
-7	100		
-6	100		
-5	100		
-4	100		
-3	100		
-2	100		
-1	100		
+1		100	100
+2		100	100
+3		100	100

If measured O.D. was outside tolerance, % can be adjusted with the same concept of High and Low O.D. as seen during the Zero point calibration.

For easy operation, Log Interpolator is available



values must be filled manually, when clicking OK, % in the selected cell will be automatically adjusted. Repeat the same procedure for all points with: fix phantom and variable kV, fix kV and variable thickness according to the next forms.

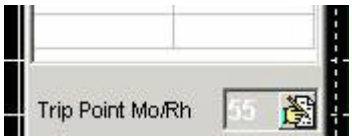
PHANTOM 45 mm	26 kV	28 kV	30 kV
Mas			
plog(p)			
pulse(i)			
d(kV)			
O.D.			

28 kV	20 mm	30 mm	40 mm	50 mm
Mas				
plog(p)				
pulse(i)				
D(kV)				
O.D.				

30Kv	50mm	60mm
mAs		
plog(p)		
pulse(i)		
d(kV)		
O.D.		

4. Rhodium filter

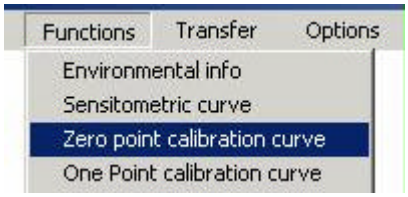
If automatic Mo/Rh filter is installed, Rhodium Zero Point curve and One point correction factors have to be defined as before for Mo/Mo.
As Mo/Rh is used for large breasts, only the upper part of calibration curve is relevant.
The same will be for correction factors of One point mode.
For calibration, from the control panel, select Mo/Rh FIX.
For normal operation, Rhodium filter is automatically selected depending on breast density.
If necessary (not recommended), Trip Point can be adjusted by means of :



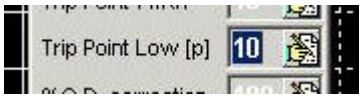
If number is decreased RH filter will come in for larger breasts and vice versa.

5. Maximum breast density limit

Select Zero Point calibration curve



Click inside Trip Point Low [p]



and define a new value.

If [p] value will be lower than the defined limit, " Breast too dense" alarm will come on and exposure is stopped releasing only the dose of pre-exposure x-ray pulse.

6. AEC calibration files backup

For future reference is essential that CD with Calibration software and AEC Calibration files remain available at the site.
AEC calibration files backup can be done on a floppy disk or added to the same software CD if PC used for calibration has CD writer and burning software.

Changes to Previous Version

Chapter	Page	Change
Detector calibration	11	Picture changed
Detector calibration	12	If out of range adjust according to the following points 10 and 11. Normal…
Detector [r] gain calibration	12	Better text and image
Connecting PC for calibration	13	New
Calibration procedure	17	... so that the exposure parameters appear in the “Emission data” window.
Calibration procedure	17	... as described in chapter “Procedure Preparation”, paragraph “Selection of test layers”.
Zero point calibration	19	…to get the Change button green, but for the best results a minimum of three phantom thickness is required.
One point calibration	23	Better text
One point calibration	23	… as seen during the Zero point calibration.